

REMARKS

This Amendment, in connection with the following remarks, is submitted as fully responsive to the Office Action. Claims 23-37 were pending. By this Amendment, claims 23 and 27 have been amended, and new claims 38-40 have been added. No new matter has been added. Claims 23 and 27 are the independent claims. Favorable reconsideration is requested.

In the Office Action, claims 23-25 and 27-31 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,854,324 to Hirschman, et al. (“Hirschman”). Additionally, claim 26 stands rejected under 35 U.S.C. §103(a) as unpatentable over Hirschman in view of U.S. Patent No. 4,684,365 to Reinicke (“Reinicke”). Finally, claims 32-37 stand rejected under 35 U.S.C. §103(a) as unpatentable over Hirschman and further in view of U.S. Patent No. 5,672,155 to Riley, et al. (“Riley”).

A. 35 U.S.C. Section 102(b) Rejections

The above presented amendments to claims 23 and 27 are intended primarily as clarifying amendments, which highlight patentable distinctions over the prior art. Support for these amendments can at least be found at ¶¶ [0062] - [0064] and at ¶¶ [0168] - [0169] of the Specification.¹

The claimed invention is directed to automating the process of performing a subsequent injection after a first injection has been performed. Thus, for example, as recited in claim 23, once a user signals a subsequent injection, the claimed method determines a preset volume of fluid necessary for such subsequent injection, compares the volume remaining in the syringe (after a first injection has been completed) with said determined preset volume of fluid, and –

¹ Citations to the present specification are to the paragraph numbers of its published version, *i.e.*, United States Patent Application Pub. No. 2004/0133165.

depending on the results of said fluid volume comparison -- either (a) advances a plunger within a chamber of the syringe to perform the subsequent injection, or (b) automatically retracts the plunger to a predetermined position within the chamber of the syringe to draw fluid from a fluid reservoir into the chamber (thus facilitating the subsequent injection).

The Office Action alleges that Hirschman anticipates claims 23-25 and 27-31. Applicants respectfully traverse. Hirschman shows no appreciation of the problem of re-filling a syringe between successive injection operations, and thus neither teaches nor suggests any solution, let alone the automated methods of the claimed invention. In fact, the text of the Hirschman reference does not even include the words “fill” or “re-fill.” Moreover, while Hirschman does use the word “reservoir” in its description, it is only to denote a chamber within a syringe, whereas the claimed invention requires *both* a fluid reservoir *and* a syringe, the fluid reservoir being in communication with a chamber of the syringe (*e.g.*, to fill and/or re-fill the syringe).

In fact, not only does Hirschman not teach the claimed invention, it actually teaches away from it. In particular, in each of the sections of Hirschman cited to by the Office Action, *i.e.*, Abstract, 10:16-26 and 13:34-41, no refilling of a syringe after an initial injection has occurred is either contemplated or described. Moreover, if there is an insufficient volume of contrast material to perform a signaled (initial) injection, the Hirschman system does not *automatically* refill the syringe from the reservoir so as to cure the deficiency and proceed, rather, it generates an alarm and displays an error message, requiring further user action. Hirschman at 10:16-26. The fact that an “INSUFFICIENT VOLUME REMAINING” error can even be generated (*see* Hirschman at 13:36-37) -- which refers to insufficient volume then existing in the syringe prior to an initial injection -- teaches away from a fluid reservoir communicably connected to the

syringe and drawn from, if necessary, to perform a subsequent injection, as is provided in the claimed invention.

Finally, Applicants distinguish an initial fill operation from an automatic refill operation between injections. For example, ¶¶ [0062] - [0064] of the present Specification describe a contrast fill operation performed during an initial setup of the system. In contrast, ¶ [0168] describes, *inter alia*, an exemplary embodiment of the invention in which the system can automatically refill the syringe, such as, for example, “when the volume of contrast material remaining in the syringe [following an injection]” is less than the “injection volume preset by the operator [for a subsequent injection].”

The potential benefits and advantages of the method of Claims 23 and 27 include (i) time saving and (ii) minimization of the amount of contrast media that would otherwise be wasted, important benefits that the automated methods of the claimed invention can provide. For example, as described in ¶ [0063] of the Specification, in the contrast fill operation performed during an initial setup, the plunger “is initially driven to its furthest forward position.” In contrast, however, to such initial setup, in the automatic refill operation described in ¶ [0168] of the Specification, automatic retraction of the plunger to refill the syringe [when the appropriate conditions are met] occurs, thereby saving time and minimizing the amount of wasted contrast material.

Thus, claims 23 and 27 are submitted as patentably distinguished over Hirschman. Dependent claims 24-26 and 28-31, and new claims 38-40 are asserted as patentable for similar reasons.

B. 35 U.S.C. Section 103(a) Rejections

Neither Reinicke, cited for its description of an air purging operation, nor Riley, cited for describing using an initially slower rate of retraction of the plunger followed by a more rapid one, cure the defects of Hirschman as a reference against the pending claims. Neither teach or suggest determining a preset volume of fluid necessary for a subsequent injection, comparing the volume remaining in a syringe (after a first injection has been completed) with said determined preset volume of fluid, and – depending on the results of said fluid volume comparison -- either (a) advancing a plunger within a chamber of the syringe to perform the subsequent injection, or (b) automatically retracting the plunger to a predetermined position within the chamber of the syringe to draw fluid from a fluid reservoir into the chamber (thus facilitating the subsequent injection).

Thus, for similar reasons as argued above, dependent claims 26, 32-37, as well as new claims 38-40 are submitted as patentable over Hirschman, Reinicke and Riley, whether taken alone or in combination.

Finally, Applicants note that the Office Action asserts that “Applicant has not disclosed that [varying the rates of retraction of the plunger] provide an advantage, is used for a particular purpose, or solves a stated problem.” Office Action at 4. Applicants respectfully traverse this assertion as well. In fact, quite to the contrary, the Specification discloses “that by using multiple speeds for retracting of plunger 412 during syringe refill, an air forming bubble within syringe 411 can be reduced more readily.” *Specification*, at ¶ [0169]. Similarly, this paragraph also provides support for new claims 38 and 40, as it recites that the syringe is “angled upward at about 10 to 20 degrees” inasmuch as the angle of the syringe “facilitates release or movement of

an air bubble.” *Id.* Thus, the varying rate of retraction of the plunger and/or the angle of the syringe each provide additional patentable distinctions over the prior art.

CONCLUSION

In light of the present amendment and arguments, Applicants respectfully submit that all pending claims are now in condition for allowance. If any open issues or concerns remain, the Examiner is hereby invited to discuss these informally with Applicants’ undersigned attorneys prior to issuing an additional Office Action, so as to obtain a speedy and swift resolution of such open issues and thereby facilitate passage to allowance.

No additional fees are believed due with the filing of this Amendment and Response to Office Action. However, if any such fee is due, the Director is hereby authorized to charge any such fees or credit any overpayments to Deposit Account No. 50-0540.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Aaron Haleva', written over a horizontal line.

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